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10/521,914	01/20/2005	Keyvan Mazda	1107-050118	7041

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EXAMINER

CUMBERLEDGE, JERRY L

ART UNIT	PAPER NUMBER
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3733

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	12/29/2006	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary

Application No.

10/521,914

Applicant(s)

MAZDA ET AL.

Examiner

Jerry Cumberledge

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 04 October 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 12-23 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 12-23 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 20 January 2005 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Allowable Subject Matter

The indicated allowability of claims 13 and 16 is withdrawn in view of the newly discovered reference(s) to Golds et al. (US Pat. 5,356,412) and Wyckoff (US Pat. 902,040).

Rejections based on the newly cited reference(s) follow.

Specification

The specification is objected to as failing to provide clear support for the claim terminology. 37 CFR § 1.75(d)(1) requires that terms and phrases used in the claims find clear support or antecedent basis in the description so that the meaning of the terms in the claims may be ascertainable by reference to the description. Specifically, the term "fastening means" does not appear in the specification.

Drawings

Upon further consideration, the drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the ligature passing through the adjustable locking means must be shown or the feature(s) canceled from the claim(s). On page 4, lines 25-29 Applicant states "said second ends of the two longitudinal members have, facing each other a bore in one and a thread in the other, so that a screw may be passed through said bore and screwed into said thread and form said adjustable locking means." In Figs. 1-4, the flexible

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ligature is never shown passing through the screw, that particular bore, or the thread.

Rather, the flexible ligature is shown passing through an opening that is near the adjustable locking means as they are defined.

No new matter should be entered.

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Claim Objections

Claims 12-22 are objected to because of the following informalities:

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There exists an inconsistency between the language of claim 12 and that of claim 13 dependent thereon, thus making the scope of the claim unclear. In the preamble of claim 12, lines 1-2, applicant recites "A vertebral fixing system" with the rod being only functionally recited, i.e. "...adapted to be mounted on a vertebra of a spine to connect it to a rod...", thus indicating that the claim is directed to the subcombination, "A vertebral fixing system". However, in claim 13, line 2, applicant positively recites the rod as part of the invention, i.e. "...said connecting part includes a passage facing said rod...", thus indicating that the combination, a vertebral fixing system and a rod, is being claimed. As such, it is unclear whether applicant intends to claim the subcombination or combination. Applicant is hereby required to indicate to which, combination or subcombination, the claims are intended to be directed, and amend the claim such that the language thereof is consistent with this intent. For examination purposes claims 12-21 will be considered as being drawn to the subcombination, "A vertebral fixing system."

In claim 22 there exists an inconsistency between the language in the preamble and that of the body of the claim, thus making the scope of the claim unclear. In the preamble, lines 1-2, applicant recites "A vertebral fixing system" with the rod being only functionally recited, i.e. "...adapted to be mounted on a vertebra of the spine to connect it to a rod...", thus indicating that the claim is directed to the subcombination, "A vertebral fixing system". However, in lines 14-15, applicant positively recites the rod as part of the invention, i.e. "...wherein said connecting part includes a passage facing said rod...", thus indicating that the combination, a vertebral fixing system and a rod, is being claimed. As such, it is unclear whether applicant intends to claim the subcombination or

combination. Applicant is hereby required to indicate to which, combination or subcombination, the claim is intended to be directed, and amend the claim such that the language thereof is consistent with this intent. For examination purposes claim 22 will be considered as being drawn to the subcombination, a vertebral fixing system.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 12-23 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 12 recites the limitation "said ends" in line 17. There is insufficient antecedent basis for this limitation in the claim.

Claim 14 recites the limitation "first ends" in line 2. There is insufficient antecedent basis for this limitation in the claim.

Claim 22 recites the limitation "the loop" in lines 12-13. There is insufficient antecedent basis for this limitation in the claim.

Claim 23 recites the limitation "the loop" in lines 12-13. There is insufficient antecedent basis for this limitation in the claim.

Claim 23 recites the limitation "first ends" in line 15. There is insufficient antecedent basis for this limitation in the claim.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 12-22, as best understood by the examiner, are rejected under 35 U.S.C. 102(b) as being anticipated by Golds et al. (US Pat. 5,356,412).

Golds et al. discloses a vertebral fixing system adapted to be mounted on a vertebra of the spine to connect it to a rod, said vertebra having a posterior wall in the vicinity of which said rod extends and lateral walls from which project ribs and/or transverse processes, said vertebral fixing system comprising: a connecting part (Fig. 2, ref. 14) adapted to face said rib and/or said transverse process and to be connected to said rod, said connecting part having a first face (Fig. 5, outer face of ref. 28) facing said rib and/or said process and a second face (Fig. 5, outer face of ref. 30) opposed to said first face and being provided with fastening means; an elongate flexible ligature (Fig. 5, ref. 12) adapted to connect together said connecting part and at least one rib and/or one transverse process, said flexible ligature having a first end secured to said fastening means (Fig. 5, end towards ref. 32), a first portion forming a loop (Fig. 5, portion from ref. 12 to near ref. 24), said first portion facing said first face of said connecting part and a second free end projecting out of said second face (Fig. 5, end near ref. 26, left side); and adjustable locking means (Fig. 5, ref. 18 and opening surrounding ref. 18) fastened to said connecting part, said locking means being adapted to fix simultaneously in

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position said connecting part relative to said rod and a second portion of said ligature (Fig. 5, portion near ref. 32) between said ends being adapted to be immobilized in translation relative to said connecting part by said adjustable locking means, whereby the loop has a particular length (Fig. 5), so as to prevent relative displacement of said rod and said vertebra in opposite directions. The connecting part includes a passage (Fig. 4, ref. 24) facing said rod and said ligature passes through the adjustable locking means (Fig. 4) to reduce a section of said passage in order to press said ligature against said rod and simultaneously to fix said connecting part and at least one portion of said ligature in position relative to said rod. The connecting part comprises two longitudinal members (Fig. 4, refs. 28 and 30) whose first ends are connected together so that said members may pivot relative to each other and middle parts of their two facing faces are adapted to bear on respective opposite sides of said rod, said adjustable locking means being adapted to drive the second ends of said longitudinal members forcibly towards each other and to fix them in position relative to each other so that said two members form a clamp and grip said rod, whereby said connecting part can be fixed in position relative to said rod. The second ends of said two longitudinal members have, facing each other, a bore (Fig. 5, ref. 26) in a first longitudinal member and a thread (Fig. 5, ref. 32) in a second longitudinal member, so that a screw may be passed through said bore and screwed into said thread to form said adjustable locking means. The first end of said ligature is fastened to a pivot (Fig. 4 and 5, ref. 20) of said longitudinal members. At least one of the middle parts of said two facing faces has a first portion through which said passage passes (Fig. 5, portion immediately surrounding

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the passage) and a second portion (Fig. 5, corner of refs. 28 and 30) adapted to bear against said rod. The passage extends between two orifices (Fig. 5, refs. 26) in said connecting part and opening to the outside of said part so that said ligature is able to slide through said part. Each of said middle parts of said two longitudinal members includes an orifice (Fig. 5, refs. 26 and 24). The passage has a section that decreases from one orifice to the other (Fig. 9, ref. 70) so as to be able to exert a progressive pressure on said ligature portion between said two orifices to press it against said rod. The ligature consists of a strip of flexible material (column 3, lines 64-67).

Golds et al. disclose a vertebral fixing system adapted to be mounted on a vertebra of the spine to connect it to a rod, said vertebra having a posterior wall in the vicinity of which said rod extends and lateral walls from which project ribs and/or transverse processes, said vertebral fixing system comprising: a connecting part (Fig. 2, ref. 14) adapted to face said rib and/or said transverse process and to be connected to said rod; an elongate flexible ligature (Fig. 5, ref. 12) adapted to connect together said connecting part and at least one rib and/or one transverse process; and adjustable locking means (Fig. 5, ref. 18 and opening surrounding ref. 18) fastened to said connecting part, said locking means being adapted to fix simultaneously in position said connecting part relative to said rod and one portion of said ligature (Fig. 5, portion near ref. 32) between said ends being adapted to be immobilized in translation relative to said connecting part by said adjustable locking means, whereby the loop has a particular length (Fig. 5), so as to prevent relative displacement of said rod and said vertebra in opposite directions, wherein said connecting part includes a passage (Fig. 5,

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ref. 24) capable of facing said rod and said ligature passes through the adjustable locking means (Fig. 5) to reduce a section of said passage in order to press said ligature against said rod and simultaneously to fix said connecting part and at least one portion of said ligature in position relative to said rod.

Claim 23, as best understood by the examiner, is rejected under 35 U.S.C. 102(b) as being anticipated by Wyckoff (US Pat. 902,040).

Wyckoff discloses a vertebral fixing system adapted to be mounted on a vertebra of the spine to connect it to a rod, said vertebra having a posterior wall in the vicinity of which said rod extends and lateral walls from which project ribs and/or transverse processes, said vertebral fixing system comprising: a connecting part (Fig. 3, refs. a and b) adapted to face said rib and/or said transverse process and to be connected to said rod; an elongate flexible (first column, lines 26-27) ligature (Fig. 4, ref. 16) adapted to connect together said connecting part and at least one rib and/or one transverse process; and adjustable locking means (Fig. 3, refs. C, E, J) fastened to said connecting part (Fig. 1), said locking means being adapted to fix simultaneously in position said connecting part relative to said rod and one portion of said ligature (Fig. 4, near ref A) between said ends being adapted to be immobilized in translation relative to said connecting part by said adjustable locking means, whereby the loop (Fig. 4, near ref 16) has a particular length, so as to prevent relative displacement of said rod and said vertebra in opposite directions, wherein said connecting part comprises two longitudinal members (Fig. 2, refs. a and b) whose first ends are connected together so that said

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members may pivot relative to each other (Fig. 2, ref. r) and middle parts (Fig. 2, middle portions of ref. a and b) of their two facing faces are adapted to bear on respective opposite sides of said rod, said adjustable locking means being adapted to drive the second ends of said longitudinal members forcibly towards each other and to fix them in position relative to each other so that said two members form a clamp and grip said rod, whereby said connecting part can be fixed in position relative to said rod, wherein said second ends of said two longitudinal members have, facing each other, a bore in a first longitudinal member (Fig. 2, ref. j) and a thread in a second longitudinal member (second column, lines 68-72), so that a screw (Fig. 2, ref. c) may be passed through said bore and screwed into said thread to form said adjustable locking means, and wherein said first end of said ligature is fastened to a pivot (Fig. 2, ref. 12) of said longitudinal members.

With regard to statements of intended use and other functional statements (e.g. "...adapted to connect to..." "...adapted to fix simultaneously..." "...adapted to be immobilized..."), they do not impose any structural limitations on the claims distinguishable over the devices of Golds et al. and Steffee, which are capable of being used as claimed if one so desires to do so. *In re Casey*, 152 USPQ 235 (CCPA 1967) and *In re Otto*, 136 USPQ 458, 459 (CCPA 1963). Furthermore, the law of anticipation does not require that the reference "teach" what the subject patent teaches, but rather it is only necessary that the claims under attack "read on" something in the reference. *Kalman v. Kimberly Clark Corp.*, 218 USPQ 781 (CCPA 1983). Furthermore, the manner in which a device is intended to be employed does not differentiate the claimed

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apparatus from prior art apparatus satisfying the claimed structural limitations. Ex parte Masham, 2 USPQ2d 1647 (1987).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 12, 14, 15, and 17-21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Fiz (U.S. Pat. 6,179,838) in view of Burgess et al. (WO 0209604 A1).

Fiz discloses a vertebral fixing system (Fig. 6 below) that is capable of mounting on a vertebra of the spine to connect it to a rod. The pedicle screw 8 (Fig. 6 below) is capable of mounting the system onto the spine. The system is capable of being placed on the spine in such a way that it would be in the vicinity of a posterior wall of a vertebra. The system comprises a connecting part (Fig. 6 below) capable of facing a rib and/or transverse process and capable of being connected to a rod. Fiz further discloses adjustable locking means (Fig. 6 below) fastened to the connecting part. The connecting part has a passage (as seen in cross section, Fig. 8 below) facing the rod. The adjustable locking means are capable of fixing the rod in place. The connecting part comprises two longitudinal members (Fig. 6 below), whose first ends are connected together and the members may pivot relative to each other. The middle parts (Figs. 6

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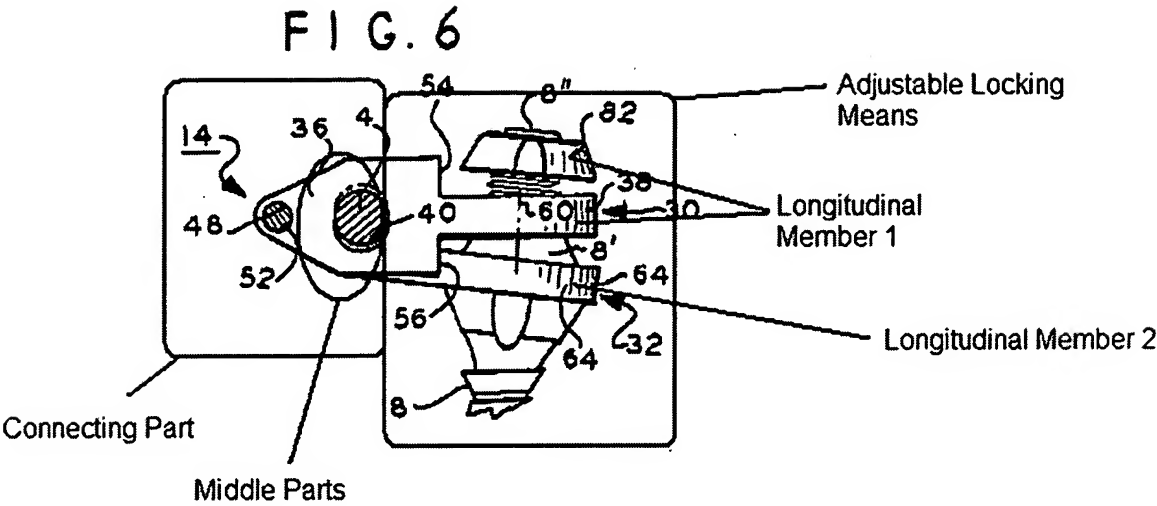
and 9) of their two facing faces are capable of bearing on respective opposite sides of the rod. The adjustable locking means are capable of driving the second ends of the longitudinal members forcibly towards each other and to fix them in position relative to each other so that the two members form a clamp and grip the rod. This also allows the connecting part to be fixed in position relative to the rod. Fig. 9 further discloses the second ends of the two longitudinal members having a bore in one and a thread in the other, so that a screw may be passed through the bore and screwed into the thread to form the adjustable locking means. The second ends of the longitudinal members have facing each other, a bore in one (Fig. 9 below) and a thread in another. Considering the nut 82 (Fig. 6 below) as part of the longitudinal member, the longitudinal member then has a threaded portion. A screw can then be passed through the bore into the thread and form the adjustable locking means. At least one of the middle parts of the two facing faces has a first portion (Fig. 8) through which the passage passes and a second portion capable of bearing against the rod (Fig. 8). The passage extends between two orifices in the connecting part (Fig. 9 below). The passage is extended between the two orifices, even though it does not span the entire distance between them. The passage has a section that decreases from one orifice to the other (Fig. 8 below), which enables the passage to exert a progressing pressure on the ligature and press it against the rod. The connecting part has a first face (Fig. 6, surface of ref. 32) that can face a rib and/or said process and a second face opposed to said first face (Fig. 6, surface of ref. 30) and being provided with a fastening means.

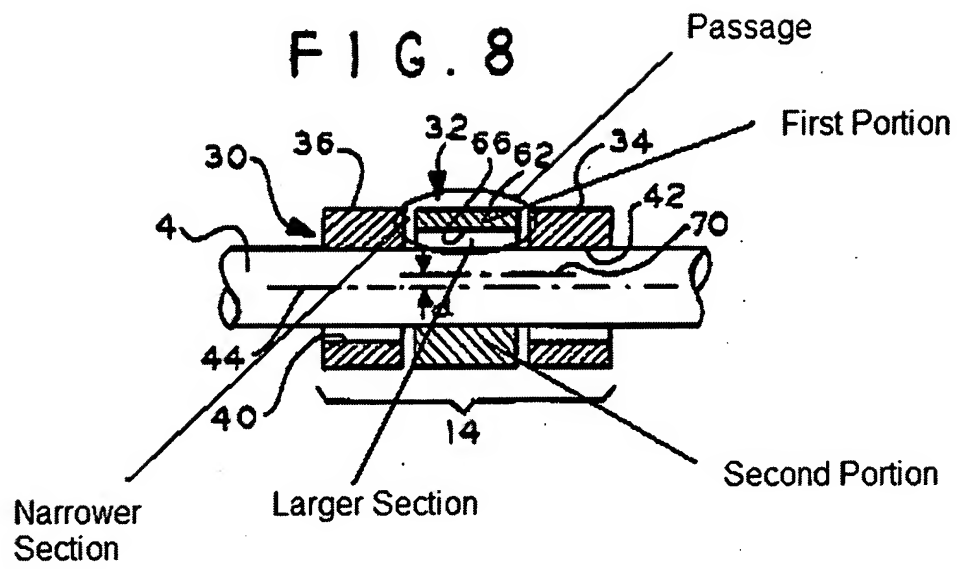
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Fiz does not disclose a flexible ligature having a first end secured to the fastening means, a first portion forming a loop, the first portion facing the first face of the connecting part and a second free end projecting out of the second face.

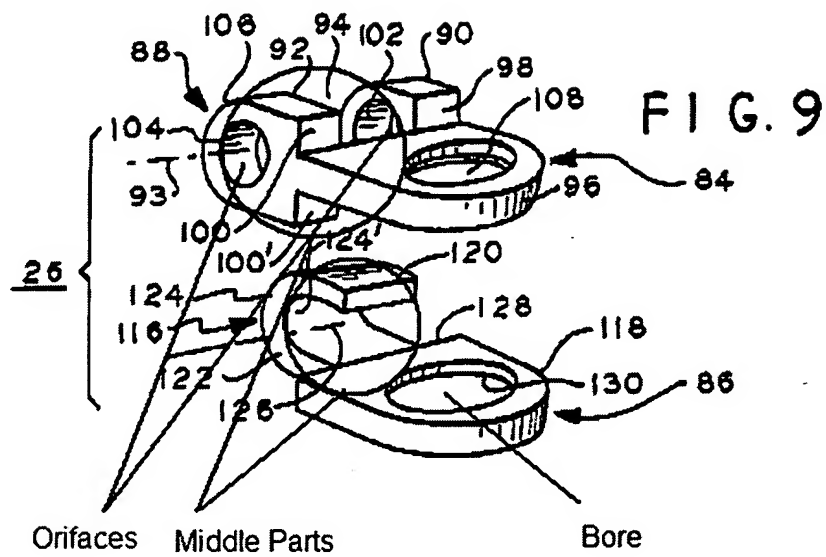
Burgess et al. disclose a flexible ligature having a first end (Fig. 6, far bottom) secured to the fastening means, a first portion forming a loop (Fig. 6, near ref. numerals 32), the first portion facing the first face of the connecting part (Fig. 6, the portion of ref. 1 that the ligature faces) and a second free end projecting out of the second face (Fig. 6, far bottom), the ligature being used for attaching the vertebral fixing system to the spine (page 2, paragraph 2, lines 1-3).

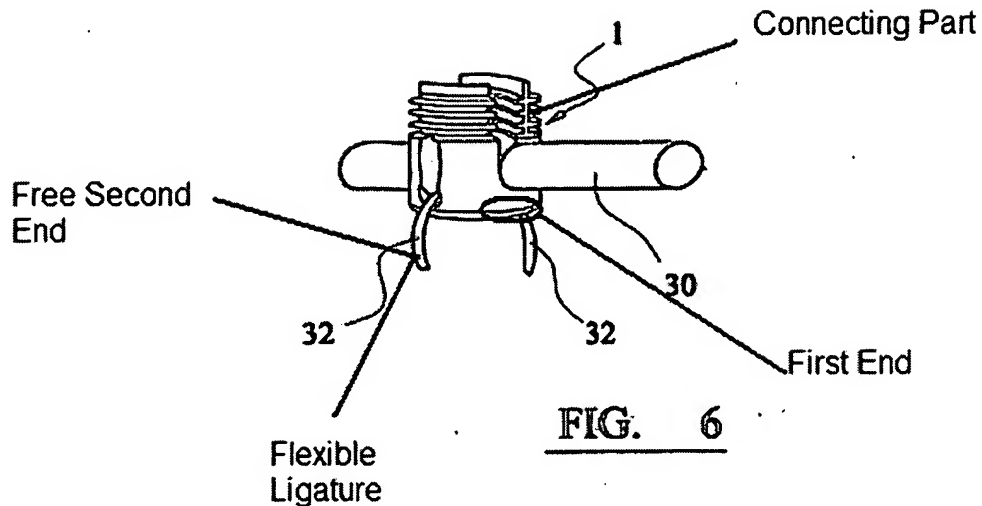
It would have been obvious to a person having ordinary skill in the art at the time the invention was made to have constructed the vertebral fixing system of Fiz with the ligature attached to the connecting device of Burgess, in order to use the ligament to attach the vertebral fixing device to the spine.





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Response to Arguments

Applicant's arguments filed 10/04/2006 have been fully considered but they are not persuasive.

With regards to Applicant's argument that Fiz and Burgess do not teach or suggest, alone or in combination, a flexible ligature having a first end secured to fastening means and a second free end projecting out of a second face, the Examiner respectfully disagrees. Please see above rejection under 35 USC 103.

With regards to Applicant's argument that the Examiner does not provide any motivation for combining the bone fixation device with any ligature, the Examiner

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respectfully disagrees. The motivation to combine the references comes from the Burgess et al. reference. Burgess et al. teaches that a ligature can be used to attach a vertebral fixing system to a spine on page 2, paragraph 2, lines 1-3.

In response to applicant's argument that the examiner's conclusion of obviousness is based upon improper hindsight reasoning, it must be recognized that any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning. But so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from the applicant's disclosure, such a reconstruction is proper. See *In re McLaughlin*, 443 F.2d 1392, 170 USPQ 209 (CCPA 1971).

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Please see attached PTO-892.

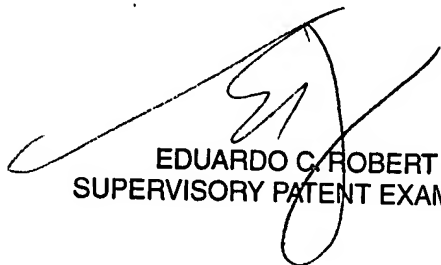
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jerry Cumberledge whose telephone number is (571) 272-2289. The examiner can normally be reached on Monday - Friday, 8:30 AM - 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eduardo Robert can be reached on (571) 272-4719. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

JLC



EDUARDO C. ROBERT
SUPERVISORY PATENT EXAMINER